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Section 5 510(k) Summary

June 24, 2008

OCT 21 2008

A. Submitter's Name / Address

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B. Contact Person

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C. Megadyne's Manufacturing Facility

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D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	E-Z Clean electrosurgical electrodes
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Devices

The predicate devices include American Medical Products' E-Z Clean Cautery Tip which was cleared for marketing via 510(k) # K862221 by FDA's Office of Device Evaluation on August 11, 1986; and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ which was cleared for marketing via 510(k) #K960255 on March 27, 1996.

F. Applicant Device Description

The Megadyne E-Z Clean electrosurgical electrode is a monopolar electrosurgical electrode that is coated with polytetrafluoroethylene (PTFE). It is insulated over the majority of its exposed length. It is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-activated electrosurgical pencil which is connected to an electrosurgical unit or ESU. This device is supplied sterile and is not intended to be reused.

The E-Z Clean electrosurgical electrodes are available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, ball-ends, and others are typical.

Some tip configurations (ACE blades) contain a slightly different geometry that will enhance the affects of the generator's Advanced Cutting Effect (ACE) Mode. In this mode, the blade will make skin incisions without the blanching or thermal damage commonly seen with standard electrosurgery. The new E-Z Clean ACE Blade provides a wound site that will heal similar to a scalpel wound (comparable Histopathology) when used in conjunction with the ACE mode. When not being used to perform skin incisions the ACE Blade functions as a standard E-Z Clean blade in all cutting and coagulating modes.

This submission also includes the option of a guard or nosecone on some configurations of electrodes. This nose cone provides additional dielectric protection at the junction where the E-Z Clean electrosurgical electrode is connected to an electrosurgical pencil.

G. Applicant Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft

tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

H. Technological Characteristics

The proposed device shares the same technological characteristics found in the predicate devices. It is an electrosurgical electrode intended for electrosurgical cutting and coagulation.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other electrosurgical electrodes on the market. There are no new technologies incorporated into the device.

Megadyne has conducted extensive testing to ensure conformance to the voluntary standard ISO 60601-2-2:2006, *Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF 18-2001, *Electrosurgical Devices.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Megadyne Medical Products, Inc.
% Ms. Ronda K. Magneson
Director, Regualtory Affairs
11506 South State Street
Draper, Utah 84020

OCT 21 2008

Re: K081791
Trade/Device Name: E-Z Clean electrosurgical electrosurgical electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 9, 2008
Received: October 10, 2008

Dear Ms. Magneson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 Indications for Use Statement

510(k) Number (if known): K081791

Device Name: E-Z Clean electrosurgical electrodes

Indications for use:

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081791

Prescription Use √ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)